

19. (Amended) A method for determining an amount of one of two types [measuring amounts] of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being [containing] a specific thyroglobulin, which is thyroglobulin having a [specific] sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; [and other ingredients;] the method comprising the steps of:

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(a) adding [using] an anti-thyroglobulin antibody reactive with both the specific thyroglobulin and the other thyroglobulin [having the sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding, contained in] to the sample forming conjugates of the anti-thyroglobulin antibody and all the thyroglobulin in the sample [, to measure the total amount of the specific thyroglobulin and the other thyroglobulin based upon the reaction thereof with the anti-thyroglobulin antibody],

(b) adding [using] said specific lectin or said specific antibody [for reacting with the specific thyroglobulin contained in] to the sample forming conjugates of said specific lectin or said specific antibody with the specific thyroglobulin conjugates formed in (a) [, to measure an amount of the specific thyroglobulin based upon the reaction thereof with said specific lectin or said specific antibody], and

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(c) determining the amount of specific [other] thyroglobulin by measuring the amount of the specific thyroglobulin conjugates formed in (b) [from the difference between (a) and (b)].

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21. (Amended) A method for determining both a total amount and an amount of one of two types [measuring amounts] of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being [containing] a specific thyroglobulin, which is thyroglobulin having a [specific] sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; [and other ingredients;] the steps comprising:

(a)(i) adding to the sample [allowing the specific thyroglobulin to react with] said specific lectin or said specific antibody forming conjugates of said specific lectin or said specific antibody with the specific thyroglobulin, and

(ii) adding to the sample [allowing both the specific thyroglobulin and the other thyroglobulin having the sugar chain other than said specific sugar chain to which said specific lectin or said specific antibody is capable of binding, to react with] an anti-thyroglobulin antibody reactive with both the specific thyroglobulin and the other thyroglobulin forming

conjugates of the anti-thyroglobulin antibody and all the thyroglobulin in the sample including specific thyroglobulin conjugates formed in (a), and

(b)(i) determining a total [an] amount of conjugates formed [the reaction product] of the anti-thyroglobulin antibody with both of the specific thyroglobulin and the other thyroglobulin [having the sugar chain other than said specific sugar chain to which said specific lectin or said specific antibody is capable of binding], and

(ii) determining an amount of conjugates formed [the reaction product] of said specific lectin or said specific antibody with the specific thyroglobulin,

wherein determining the amount of conjugates formed in (b)(i) corresponds to the total amount of thyroglobulin and determining the amount of conjugates formed in (b)(ii) corresponds to the amount of specific thyroglobulin.

22. (Amended) A method for determining malignancy of a thyroid tumor, comprising:

(1) measuring the total amount of thyroglobulin and an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being [containing] a specific thyroglobulin, which is thyroglobulin having a [specific] sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the

specific sugar chain to which said specific lectin or said specific antibody is capable of binding;  
[and other ingredients;] the steps comprising:

(a)(i) adding to the sample [allowing the specific thyroglobulin to react with] said specific lectin or said specific antibody forming conjugate-1 of said specific lectin or said specific antibody with the specific thyroglobulin, and

(ii) adding to the sample [allowing both the specific thyroglobulin and the other thyroglobulin having the sugar chain other than said specific sugar chain to which said specific lectin or said specific antibody is capable of binding, to react with] an anti-thyroglobulin antibody reactive with both the specific thyroglobulin and the other thyroglobulin forming conjugates of the anti-thyroglobulin antibody and all the thyroglobulin in the sample including specific thyroglobulin conjugates formed in (a), and

(b)(i) determining an amount of conjugate-1 formed in step (a)(i) [the reaction product] of said specific lectin or said specific antibody with the specific thyroglobulin, and

(ii) determining a total [an] amount of conjugates formed in step (a)(ii) [the reaction product] of the anti-thyroglobulin antibody with both of the specific thyroglobulin and the other thyroglobulin [having the sugar chain other than said specific sugar chain to which said specific lectin or said specific antibody is capable of binding], and

(2) determining the malignancy of the thyroid tumor [based on the amounts obtained in (b)(i) and (b)(ii)] by comparing the calculated ratio with a predetermined ratio from a fluid sample originating from a living body having:

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- (i) normal thyroid;
  - (ii) benign thyroid; or
  - (iii) thyroid carcinoma;

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the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

26. The method according to [claims 19-22 and 24] claims 19, 21, and 31-38, wherein said specific antibody is one reactive with a Lewis type sugar chain.

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27. (Amended) A reagent for determining an amount of one of two types [measuring amounts] of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being [containing] a specific thyroglobulin, which is thyroglobulin having a [specific] sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; [and other ingredients;] the reagent comprising:

(a) an anti-thyroglobulin antibody reactive with both the specific thyroglobulin and the other thyroglobulin to form conjugates of the anti-thyroglobulin antibody and all the

thyroglobulin in the sample [having the sugar chain other than said specific sugar chain to which said specific lectin or said specific antibody is capable of binding, contained in the sample, wherein the total amount of the specific thyroglobulin and the other thyroglobulin is determined based upon a reaction thereof with the anti-thyroglobulin antibody],

(b) said lectin or said antibody for reacting with the specific thyroglobulin contained in the sample to form conjugates of said specific lectin or said specific antibody with the specific thyroglobulin conjugates formed in (a) [, wherein an amount of the specific thyroglobulin is determined based upon a reaction thereof with said specific lectin or said specific antibody],

whereby said reagent when added to the sample forms conjugates which can be separated and measured thereby determining the amount of one of the two types of thyroglobulin in the sample [an amount of the other thyroglobulin can be measured from the determination difference between (a) and (b)].

28. (Amended) A reagent for determining a malignancy of a thyroid tumor from a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the reagent comprising:

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(a) an anti-thyroglobulin antibody reactive with the [a] specific thyroglobulin [ , which is thyroglobulin having a specific sugar chain to which a specific lectin or a specific antibody is capable of binding] and other thyroglobulin to form conjugates of the anti-thyroglobulin antibody and all the thyroglobulin in the sample [having a sugar chain other than one to which said specific lectin or said specific antibody is capable of binding, in a sample originated from a living body, for determining a total amount of thyroglobulin], and

(b) said specific lectin or said specific antibody for reacting with the specific thyroglobulin to form conjugates of said specific lectin or said specific antibody with the specific thyroglobulin conjugates formed in (a) [and for determining an amount of the specific thyroglobulin in the sample],

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whereby the malignancy of a thyroid tumor can be determined when said reagent added to the sample forms conjugates which can be separated and measured thereby determining the amount of one of the two types of thyroglobulin in the sample which corresponds the malignancy of the thyroid tumor [on the basis of the total amount of thyroglobulin obtained by using (a) and the amount of the specific thyroglobulin obtained by using (b)].

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**Please add new claims 30-58 as follows:**

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--30. A method of determining malignancy of a thyroid tumor comprising:

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(1) measuring the total amount of thyroglobulin in a fluid sample originating from a living body and (a) an amount of specific thyroglobulin having a specific sugar chain to which a specific lectin or a specific antibody is capable of binding; or, (b) the amount of thyroglobulin having a sugar chain other than the specific sugar chain;

(2) calculating a percent ratio of (a) the total thyroglobulin to the amount of specific thyroglobulin; or (b) the total thyroglobulin to the amount of thyroglobulin other than the specific thyroglobulin; and

(3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a fluid sample originating from a living body having:

- (a) normal thyroid;
- (b) benign thyroid; or
- (c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

31. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to



which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

(a) adding to the sample the specific lectin or the specific antibody, and an anti-thyroglobulin antibody-1, capable of binding to all thyroglobulin, to form a conjugate-1 of the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific lectin, or the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific antibody and a conjugate-2 of the anti-thyroglobulin antibody-1 -- the other thyroglobulin,

(b) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or

(c) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content.

32. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said

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specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

- (a) adding to the sample the specific lectin or the specific antibody to form a conjugate of the specific lectin -- the specific thyroglobulin or the specific antibody -- the specific thyroglobulin,
- (b) separating both the conjugate and the other thyroglobulin, and
- (c) determining an amount of the specific thyroglobulin on the basis of the conjugate content; and/or
- (d) determining an amount of the separated other thyroglobulin.

33. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

- (a) adding to the sample the specific lectin or the specific antibody, an anti-thyroglobulin antibody-1, capable of binding to all thyroglobulin, and an anti-thyroglobulin antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to

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which the specific lectin or the specific antibody is already bound, to form a conjugate-1 of the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific lectin, or the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific antibody, and a conjugate-2 of the anti-thyroglobulin antibody-1 -- the other thyroglobulin -- the antibody-2,

- (b) separating the conjugate-1 and the conjugate-2, and
- (c) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or
- (d) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content.

34. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

- (a) adding to the sample the specific lectin or the specific antibody and an anti-thyroglobulin antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to which the specific lectin or the specific antibody is already bound, to form a

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conjugate-1 of the specific lectin -- the specific thyroglobulin, or the specific antibody -- the specific thyroglobulin, and a conjugate-2 of the anti-thyroglobulin antibody-2 -- the other thyroglobulin,

- (b) separating the conjugate-1 and conjugate-2 formed in the step (a),
- (c) adding the anti-thyroglobulin antibody-1, capable of binding to all thyroglobulin, to the conjugate-2 formed in the step (a), to form a conjugate-3 of the anti-thyroglobulin antibody-2 -- the other thyroglobulin -- the anti-thyroglobulin antibody-1,
- (d) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or
- (e) determining an amount of the other thyroglobulin on the basis of the conjugate-3 content.

35. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

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- (a) adding to the sample the specific lectin or the specific antibody and an anti-thyroglobulin antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to which the specific lectin or the specific antibody is already bound, to form a conjugate-1 of the specific lectin -- the specific thyroglobulin, or the specific antibody -- specific thyroglobulin, and a conjugate-2 of the anti-thyroglobulin antibody-2 -- the other thyroglobulin,
- (b) separating the conjugate-1 and the conjugate-2, and
- (c) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or
- (d) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content.

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36. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

- (a) dividing the sample into a first portion and a second portion;

- (b)(i) adding to the first portion the specific lectin or the specific antibody to cause the precipitation of the specific thyroglobulin -- the specific lectin, or the specific thyroglobulin --the specific antibody conjugate;
  - (ii) separating the precipitated conjugate from the other thyroglobulin; and
  - (iii) determining an amount of the other thyroglobulin of the remainder of the sample; and/or
- (c)(i) determining an amount of the total thyroglobulin of the second portion; and/or
  - (ii) determining an amount of the specific thyroglobulin from the difference between an amount of the total thyroglobulin and the amount of the other thyroglobulin obtained in step (b)(iii).

37. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

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(a) adding to the sample the specific lectin or the specific antibody to form a conjugate of the specific thyroglobulin -- the specific lectin, or the specific thyroglobulin -- the specific antibody;

(b) adding to the sample an antibody-1, capable of binding to all thyroglobulin, to form a conjugate-1 of the antibody-1 -- the specific thyroglobulin -- the specific lectin or antibody-1 -- the specific thyroglobulin -- the specific antibody and a conjugate-2 of the antibody-1 -- the other thyroglobulin;

(c) separating the conjugate-1 and the conjugate-2; and

(d) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or

(e) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content.

38. A method for determining an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

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- (a) dividing the sample into a first portion and a second portion;
- (b)(i) adding to the first portion the specific lectin or the specific antibody to form a conjugate of the specific thyroglobulin -- the specific lectin, or the specific thyroglobulin -- the specific antibody;
- (ii) adding to the first portion an antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to which the specific lectin or the specific antibody is already bound, to form a conjugate of the other thyroglobulin -- antibody-2; and
- (iii) determining the amount of the other thyroglobulin on the basis of the measurement of the other thyroglobulin -- antibody-2 conjugate formed in step (b)(ii); and/or
- (c)(i) determining an amount of the total thyroglobulin of the second portion; and
- (ii) determining an amount of the specific thyroglobulin from the difference between an amount of the total thyroglobulin and the amount of the other thyroglobulin obtained in step (b)(iii).

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39. A method for determining malignancy of a thyroid tumor comprising:

- (1) measuring the total amount of and an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to



which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

- (a) adding to the sample the specific lectin or the specific antibody, and an anti-thyroglobulin antibody-1, capable of binding to all thyroglobulin, to form a conjugate-1 of the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific lectin, or the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific antibody and a conjugate-2 of the anti-thyroglobulin antibody-1 -- the other thyroglobulin,
  - (b) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or
  - (c) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content.
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- (2) calculating a percent ratio of (a) the amount of total thyroglobulin to the amount of specific thyroglobulin; or (b) the amount of total thyroglobulin to the amount of other thyroglobulin; and
  - (3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample derived from a living body having:
    - (a) normal thyroid;
    - (b) benign thyroid; or

(c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

40. A method for determining malignancy of a thyroid tumor comprising:

(1) measuring the total amount of and an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

(a) adding to the sample the specific lectin or the specific antibody to form a conjugate of the specific lectin -- the specific thyroglobulin or the specific antibody -- the specific thyroglobulin,

(b) separating the conjugate from the other thyroglobulin, and

(c) determining an amount of the specific thyroglobulin on the basis of the conjugate content; and/or

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(d) determining an amount of the separated other thyroglobulin;  
(2) calculating a percent ratio of (a) the amount of total thyroglobulin to the amount of specific thyroglobulin; or (b) the amount of total thyroglobulin to the amount of other thyroglobulin; and

(3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample derived from a living body having:

- (a) normal thyroid;
- (b) benign thyroid; or
- (c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

41. A method for determining malignancy of a thyroid tumor comprising:

(1) measuring the total amount of and an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to

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which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

(a) adding to the sample (i) the specific lectin or the specific antibody, (ii) an anti-thyroglobulin antibody-1, capable of binding to all thyroglobulin, and (iii) an anti-thyroglobulin antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to which the specific lectin or the specific antibody is already bound, to form a conjugate-1 of the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific lectin, or the anti-thyroglobulin antibody-1 -- the specific thyroglobulin -- the specific antibody, and a conjugate-2 of the anti-thyroglobulin antibody-1 -- the other thyroglobulin -- the anti-thyroglobulin antibody-2,

(b) separating the conjugate-1 and the conjugate-2, and

(c) determining an amount of the specific thyroglobulin on the basis of the conjugate-2 content; and/or

(d) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content;

(2) calculating a percent ratio of the amount of total thyroglobulin to the amount of specific thyroglobulin; or the amount of total thyroglobulin to the amount of other thyroglobulin; and

(3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample derived from a living body having:

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- (a) normal thyroid;
- (b) benign thyroid; or
- (c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

42. A method for determining malignancy of a thyroid tumor comprising:

(1) measuring the total amount of and an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

(a) adding to the sample the specific lectin or the specific antibody and an anti-thyroglobulin antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to which the specific lectin or the specific antibody is already bound, to form a conjugate-1 of the specific lectin -- the specific thyroglobulin, or the specific antibody -- the

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specific thyroglobulin, and a conjugate-2 of the anti-thyroglobulin antibody-2 -- the other thyroglobulin,

- (b) separating the conjugate-1 and conjugate-2 formed in the step (a),
- (c) adding the anti-thyroglobulin antibody-1, capable of binding to all thyroglobulin, to the conjugate-2 formed in the step (a) to form a conjugate--3 of the anti-thyroglobulin antibody-2 -- the other thyroglobulin -- the anti-thyroglobulin antibody-1,
- (d) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or
- (e) determining an amount of the other thyroglobulin on the basis of the conjugate--3 content,
- (2) calculating a percent ratio of (a) the amount of total thyroglobulin to the amount of specific thyroglobulin; or (b) the amount of total thyroglobulin to the amount of other thyroglobulin; and
- (3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample derived from a living body having:
  - (a) normal thyroid;
  - (b) benign thyroid; or
  - (c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body

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having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

43. A method for determining malignancy of a thyroid tumor comprising:

(1) measuring the total amount of and an amount of one of two types of thyroglobulin in a fluid sample originating from a living body, the two types of thyroglobulin in the sample being a specific thyroglobulin, which is thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding; and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the method comprising the steps of:

(a) adding to the sample the specific lectin or the specific antibody and an anti-thyroglobulin antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to which the specific lectin or the specific antibody is already bound, to form a conjugate-1 of the specific lectin -- the specific thyroglobulin, or the specific antibody -- the specific thyroglobulin, and a conjugate-2 of the anti-thyroglobulin antibody-2 -- the other thyroglobulin,

(b) separating the conjugate-1 and the conjugate-2, and

(c) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or

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(d) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content,

(2) calculating a percent ratio of the amount of total thyroglobulin to the amount of specific thyroglobulin; or the amount of total thyroglobulin to the amount of other thyroglobulin; and

(3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample derived from a living body having:

- (a) normal thyroid;
- (b) benign thyroid; or
- (c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

44. A method for determining malignancy of a thyroid tumor by measuring the thyroglobulin content of a fluid sample originating from a living body, the sample containing a specific thyroglobulin, which is a thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding and other thyroglobulin,

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which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the steps comprising:

- (1)(a) dividing the sample into a first portion and a second portion;
- (b)(i) adding to the first portion the specific lectin or the specific antibody to cause the precipitation of the specific thyroglobulin -- the specific lectin, or the specific thyroglobulin -- the specific antibody conjugate;
- (ii) separating the precipitated conjugate from the other thyroglobulin; and
- (iii) determining an amount of the other thyroglobulin of the remainder of the sample; and/or
- (c)(i) determining an amount of the total thyroglobulin of the second portion; and
- (ii) determining an amount of the specific thyroglobulin from the difference between the amount of the total thyroglobulin and the amount of the other thyroglobulin obtained in step (b)(iii),
- (2) calculating a percent ratio of the amount of total thyroglobulin to the amount of specific thyroglobulin; or the amount of total thyroglobulin to the amount of other thyroglobulin; and
- (3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample derived from a living body having:
- (a) normal thyroid;

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(b) benign thyroid; or

(c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

45. A method for determining malignancy of a thyroid tumor by measuring the thyroglobulin content of a fluid sample originating from a living body, the sample containing a specific thyroglobulin, which is a thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the steps comprising:

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- (1)(a) adding to the sample the specific lectin or the specific antibody to form a conjugate of the specific thyroglobulin -- the specific lectin, or the specific thyroglobulin -- the specific antibody;
  - (b) adding to the sample an antibody-1, capable of binding to all thyroglobulin, to form a conjugate-1 of the antibody-1 -- the specific thyroglobulin -- the specific lectin or antibody-1 -- the specific thyroglobulin -- the specific antibody and a conjugate-2 of the antibody-1 -- the other thyroglobulin;

- (c) separating the conjugate-1 and the conjugate-2; and
  - (d) determining an amount of the specific thyroglobulin on the basis of the conjugate-1 content; and/or
  - (e) determining an amount of the other thyroglobulin on the basis of the conjugate-2 content,
- (2) calculating a percent ratio of the amount of total thyroglobulin to the amount of specific thyroglobulin; or the amount of total thyroglobulin to the amount of other thyroglobulin; and
- (3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample derived from a living body having:
- (a) normal thyroid;
  - (b) benign thyroid; or
  - (c) thyroid carcinoma;

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the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

46. A method for determining malignancy of a thyroid tumor by measuring the thyroglobulin content of a fluid sample originating from a living body, the sample containing a

specific thyroglobulin, which is a thyroglobulin having a sugar chain with a specific structure to which a specific lectin or a specific antibody is capable of binding and other thyroglobulin, which is thyroglobulin having a sugar chain other than the specific sugar chain to which said specific lectin or said specific antibody is capable of binding; the steps comprising:

- (1)(a) dividing the sample into a first portion and a second portion;
- (b)(i) adding to the first portion the specific lectin or the specific antibody to form the conjugate of the specific thyroglobulin -- the specific lectin, or the specific thyroglobulin -- the specific antibody;
- (ii) adding to the first portion an antibody-2, capable of binding to thyroglobulin but not capable of binding to thyroglobulin to which the specific lectin or the specific antibody is already bound; and
- (iii) determining an amount of the other thyroglobulin on the basis of the measurement of the other thyroglobulin -- antibody-2 conjugate formed in step (b)(ii); and/or
- (c)(i) determining an amount of the total thyroglobulin of the second portion; and
- (ii) determining an amount of the specific thyroglobulin from the difference between the amount of the total thyroglobulin and the amount of the other thyroglobulin obtained in step (b)(iii).

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(2) calculating a percent ratio of the total thyroglobulin to the amount of the specific thyroglobulin; or the total thyroglobulin to the amount of other thyroglobulin; and

(3) determining the malignancy of the thyroid tumor by comparing the calculated ratio with a predetermined ratio from a sample originating from a living body having:

- (a) normal thyroid;
- (b) benign thyroid; or
- (c) thyroid carcinoma;

the calculated ratio of the fluid sample originating from a living body having thyroid carcinoma being significantly higher or lower than that of the fluid sample originating from a living body having the normal thyroid or the fluid sample originating from a living body having the benign thyroid.

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47. The method of claims 22, 30, and 39-46, wherein said specific antibody is one reactive with an Lewis type sugar chain.

48. The method according to claims 22, 30 and 39-46, wherein the sugar chain with the specific structure is one found in thyroglobulin which is produced by a carcinoma cell.--

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**REMARKS**

Claims 15, 19, 21-22, 26-28 and new claims 30-48 are pending in this application.